REMARKS

Applicants respectfully request entry of the amendments and remarks submitted herein. Claims 1 and 2 have been amended herein, and claims 9-19 have been canceled without prejudice to continued prosecution. New claims 28 and 29 have been added herein. Support for new claims 28 and 29 can be found, for example, on page 9, lines 6-9; page 10, lines 19-26; page 11, lines 20-21; page 16, lines 18-22; page 21, lines 19-20; page 37, lines 24-25 and 29; page 29, lines 3-7; page 30, lines 8-11; page 31, lines 19-25; page 48, lines 4-21; and page 14, lines 5-8. Specifically, see, for example, the sentence bridging pages 15 and 16, which states that "only a fragment of the entire coding sequence..." can be used; and page 32, lines 25-26, which is directed toward "the carboxy-terminus of a larger [open reading frame]..."

Claims 1-5 and 27-29 are currently pending, and claims 6-8 and 20-26 are withdrawn as directed toward a non-elected invention. Reconsideration of the pending application is respectfully requested.

The 35 U.S.C. §112 Rejections

Claims 1-5 and 27 stand rejected under 35 U.S.C. §112, first paragraph, as the Examiner asserted that those claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner stated that the specification discloses an isolated recombinant polypeptide comprising the amino acid sequence SEQ ID NO: 8, which is 1879 amino acids in length, and asserted that an isolated and purified polypeptide *consisting of* 8 consecutive residues or 12 consecutive residues of the amino acid sequence SEQ ID NO: 8 meets the written description provision of 35 U.S.C. §112, first paragraph. The Examiner asserted, however, that the specification fails to disclose a purified immunogenic polypeptide or mutant *comprising* at least eight consecutive residues or at least 12 consecutive residues of a sequence SEQ ID NO: 8 (emphasis added) and that the specification fails to satisfy the written description for the full scope of the claims because the claimed polypeptide variants were not disclosed.

The Examiner asserted that adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making it, and the

Examiner cited *Fiers v Revel* (25 USPQ2d 1601, 1606 (CAFC 1993)), *Amgen Inc v Chugai Pharmaceutical Co Ltd.* (18 USPQ2d 1016), and *Fiddes v. Baird* (30 USPQ2d 1481, 1483). The Examiner concluded that Applicants broadly describe the invention as embracing any deletion by use of language in which a specified percent of amino acids can be changed in the protein. Applicants respectfully traverse this rejection.

Applicants respectfully disagree and refer the Examiner to *Capon et al. v. Eshhar et al. v. Dudas* (418 F.3d 1349, 76 USPQ2d 1078 (Fed. Circ. 2005)) and *Invitrogen Corp. v. Clontech Laboratories, Inc.* (429 F.3d 1052 (Fed. Circ. 2005)). In *Invitrogen*, the Federal Circuit determined that the patent-in-suit contained an adequate written description of the claimed genus based on the disclosure in the specification as well as the availability of sequences in the prior art thata are related by both sequence homology and function. Both *Capon* and *Invitrogen* stand for the proposition that the amount of written description necessary to support generic claims "depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter." *Capon et al. v. Eshhar et al. v. Dudas* (418 F.3d 1349, 1359 (Fed. Cir. 2005)). Neither *Capon* nor *Invitrogen* are inconsistent with the earlier *Fiers* and *Amgen* cases cited by the Examiner.

Applicants note that the claims explicitly require that the polypeptide be immunogenic. The specification provides a significant amount of written description regarding making, identifying, and using immunogenic polypeptides. See, for example, pages 17 -22 and throughout the Examples. In addition to describing the actual sequence of the polypeptide from which the claimed immunogenic polypeptides can be obtained (i.e., SEQ ID NO: 8), the specification describes an immunogenic polypeptide functionally (see, for example, page 11, lines 17-19) and provides a significant amount of disclosure regarding using the claimed immunogenic polypeptides for either or both a vaccine or in a method of detecting infected swine. See, for example, pages 17-22 as well as throughout the Examples.

Contrary to the Examiner's assertion, the specification also provides a significant amount of written description for immunogenic fragments and variants (e.g., mutants) of SEQ ID NO:8. See, for example, page 9, lines 6-9; page 10, lines 19-26; page 11, lines 20-21; page 16, lines 18-22; page 21, lines 19-20; and page 37, lines 24-25 and 29. In addition, fragments generated from

enzymatic cleavage of a larger polypeptide are described throughout the specification. See, for example, page 29, lines 3-7; page 30, lines 8-11; page 31, lines 19-25; and page 48, lines 4-21 for disclosure regarding trypsin digestion or, for example, page 14, lines 5-8 for disclosure regarding restriction enzyme digestion.

Based on the maturity of the science and the predictability of the aspects at issue, Applicants have met the written description requirement for the claimed polypeptides and fragments thereof. In view of the remarks herein, Applicants respectfully request the rejection of claims 1-5 and 27 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 1-5 and 27 stand rejected under 35 U.S.C. §112, first paragraph, as the Examiner asserted that the specification fails to provide guidance for an isolated polypeptide comprising, (open language) 8 consecutive residues or 12 consecutive residues of SEQ ID NO:8 plus unlimited and unknown amino acids that would result in an unknown variants without any structure and other identifying characteristics such as function. The Examiner concluded, therefore, that the variants as claimed are broader than SEQ ID NO: 8 and that the specification fails to provide sufficient guidance such that one of ordinary skill in the art can predict *a priori* what protein variants can be made. The Examiner cites Burgess et al. (*J. Cell Biol.*, 111:2129-2138, 1990) to support the assertion that "any substitution, insertion or deletion or change in a protein is highly complex and unpredictable and even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein." This rejection is respectfully traversed.

The claims are not directed toward any polypeptide comprising 8 or 12 residues of SEQ ID NO:8 as the Examiner asserted but are limited to "immunogenic polypeptide[s]." Applicants respectfully refer the Examiner to *Hybritech Inc. v. Monoclonal Antibodies, Inc.* (802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987)), which indicates that enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive."

It is routine for those of skill in this art to generate fragments from a larger or full-length polypeptide and to determine whether or not those fragments are immunogenic and bind to an antibody. The approaches involved in screening fragments for antibody binding are routine. In

addition, not only are polypeptides comprising 8 or 12 residues of SEQ ID NO:8 enabled, but polypeptides varying in sequence from SEQ ID NO:8 are enabled for the same reasons. That is, generating and determining the antibody-binding capability of such variants is routine in the art. Using currently available equipment and procedures, many of which are automated, hundreds or thousands of different polypeptides including variants can be readily and rapidly screened for specific binding affinity to an antibody without undue experimentation.

Applicants' disclosure fully enables the pending claims. In view of the remarks herein, Applicants respectfully request that the rejection of claims 1-5 and 27 under 35 U.S.C. §112, first paragraph, be withdrawn.

The 35 U.S.C. §102 Rejections

Claims 1-5 and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by database Uniprot_03, Accession number Q9KGX7 or Q9KGX9. The Examiner asserted that Accession No. Q9KGX7 discloses polypeptides comprising 8 or 12 consecutive residues of SEQ ID NO: 8. The Examiner stated that the polypeptide disclosed in Q9KGX7 comprises 560 amino acids that contains 8 or 12 consecutive residues of SEQ ID NO:8 and that is 100% identical with the immunogenic polypeptides of claim 1 and 2. Further, according to the Examiner, the same polypeptide (Accession No. Q9KGX7) reads on claim 4 because the prior art polypeptide contains amino acid aspartic acid (D) in place of glutamic acid (E) at position 544. Applicants respectfully traverse this rejection.

There is no evidence in Q9KGX7 or that Applicants can identify in the literature database that the carboxy terminus of the amino acid sequence disclosed in Q9KGX7, which corresponds to the amino terminus of the claimed SEQ ID NO:8, was ever purified, as is required by the pending claims. It is well established that a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See, *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed.Cir.1987)). Therefore, Applicants submit that Q9KGX7 does not anticipate the claimed invention, and respectfully request that the rejection of claims 1-5 and 27 under 35 U.S.C. §102(b) be withdrawn.

Claims 1-5 and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by Zhang et al. (*Infect. Immun.*, 63:1013-1019, 1995). According to the Examiner, Zhang et al. disclose affinity chromatography-purified *Mycoplasma* proteins from pathogenic *M. hyopneumoniae* strains 232, 2A3 and 232 FA1. The Examiner asserted that the composition of Zhang et al. contained purified immunogenic polypeptides SEQ ID NO:8 and mutants of said polypeptide. The Examiner asserted that Applicants' use of the open-ended term "comprising" in claims 1-5 and 27 fails to exclude un-recited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the Examiner concluded that the claims read on the composition of Zhang et al. comprising purified proteins such as a 97 kD polypeptide. This rejection is respectfully traversed.

The pending claims are directed toward a "*purified* immunogenic polypeptide, the amino acid *sequence* of which *comprises*..." (emphasis added). According to the specification (see, for example, page 9, lines 6-23), a polypeptide has been purified when there is less than about 30% of other "contaminating" proteins in the preparation. Applicants submit that it is unclear as to whether or not the polypeptide of SEQ ID NO:8 is even present in the purified *Mycoplasma* proteins disclosed in Zhang et al., and if the preparation of Zhang et al. does actually contain the polypeptide of SEQ ID NO:8, it is certainly not "purified" as the pending claims require. In view of the remarks herein, Applicants respectfully request the rejection of claims 1-5 and 27 under 35 U.S.C. §102(b) be withdrawn.

Request for Rejoinder

Claims 6-8 and 20-26 were withdrawn as directed to non-elected species following the Restriction Requirement of July 6, 2005, and Applicant's election of September 28, 2005. The Examiner indicated in the Restriction Requirement, however, that the (elected) claims of Group I (claims 1-5 and 27) are related to the claims of Group III (claims 6-8) and Group V (claims 20-26) as product and process of use. Since non-elected claims 6-8 and 20-26 depend either directly or indirectly from claim 1, Applicants respectfully requests that claims 6-8 and 20-26 be rejoined pursuant to MPEP §821.04.

CONCLUSION

Applicants respectfully request allowance of claims 1-8 and 20-29. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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M. Angela Parsons, Ph.D.
Reg. No. 44,282

Fish & Richardson P.C., P.A.
60 South Sixth Street, Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696
60366684.doc